AN ACT relating to medication-assisted treatment.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

Sections 1 to 11 of this Act shall be known as the Medication-Assisted Treatment Program Licensing Act.

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

As used in Sections 1 to 11 of this Act:

(1) "Addiction":

(a) Means a primary, chronic disease of brain reward, motivation, memory, and related circuitry, in which dysfunction in these circuits leads to characteristic biological, psychological, social, and spiritual manifestations, which is reflected in an individual pathologically pursuing reward or relief by substance use or both, and other behaviors;

(b) Is characterized by an inability to consistently abstain; impairment in behavioral control; craving; diminished recognition of significant problems with one's behaviors; interpersonal problems with one's behaviors and interpersonal relationships; and a dysfunctional emotional response; and

(c) Includes definitions put forth by the American Society of Addiction Medicine;

(2) "Biopsychosocial" means of, relating to, or concerned with biological, psychological, and social aspects in contrast to the strictly biomedical aspects of disease;

(3) "Center for Substance Abuse Treatment" means the center under the federal Substance Abuse and Mental Health Services Administration that promotes community-based substance use treatment and recovery services for individuals

and families in the community and provides national leadership to improve access, reduce barriers, and promote high quality, effective treatment, and recovery services;

(4) "Commissioner" means the commissioner of the Department for Behavioral Health, Developmental and Intellectual Disabilities;

(5) "Department" means the Department for Behavioral Health, Developmental and Intellectual Disabilities in the Cabinet for Health and Family Services;

(6) "Medical director" means a physician licensed pursuant to KRS Chapter 311 who assumes responsibility for administering all medical services performed by a medication-assisted treatment program, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's direct supervision and functioning with their respective scopes of practice;

(7) "Medication-assisted treatment" means the use of medications and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders;

(8) "Medication-assisted treatment program" or "program" means a publicly or privately owned opioid treatment program or office-based medication-assisted treatment program which prescribes medication-assisted treatment medications and treats substance use disorders;

(9) "Medication-assisted treatment medication" means a medication that is approved by the United States Food and Drug Administration under Section 505 of the federal Food, Drug, and Cosmetic Act for use in the treatment of substance use disorders that is an opioid agonist and is listed on the schedule of controlled substances in KRS Chapter 218A;

(10) "Office based medication-assisted treatment" means a publicly or privately owned medication-assisted treatment program in a clinic, facility, office, or

program that treats individuals with substance use disorders through the prescription, administration, or dispensing of a medication-assisted treatment medication in the form of a partial opioid agonist or other medication-assisted treatment medication approved for use in an office-based medication-assisted treatment setting;

(11) "Opioid agonist" means a substance that binds to and activates opiate receptors resulting in analgesia and pain regulation, respiratory depression, and a wide variety of behavioral changes. It does not include partial agonist medications used as an alternative to opioid agonists in the treatment of opioid addiction;

(12) "Opioid treatment program" means a publicly or privately owned medication-assisted treatment program in a clinic, facility, office, or program that treats individuals with substance use disorders through on-site administration or dispensing of a medication-assisted treatment medication in the form of an opioid agonist or partial opioid agonist;

(13) "Owner" means any person, partnership, association, or limited liability company listed as the owner of a medication-assisted treatment program on the licensing forms required by Sections 1 to 11 of this Act. Only a physician having a full and active license to practice medicine pursuant to KRS Chapter 311 may have an ownership or investment interest in a medication-assisted treatment program. Credit extended by a financial institution, as defined in KRS 136.500, to a treatment program shall not be deemed an investment interest under this section;

(14) "Partial opioid agonist" means a Federal Drug Administration-approved medication that is used as an alternative to an opioid agonist for the treatment of substance use disorders and that binds to and activates opiate receptors, but not to the same degree as full agonists;

(15) "Physician" means an individual licensed to practice medicine or osteopathy

pursuant to KRS Chapter 311;

(16) "Prescriber" means a person who has prescriptive authority, as authorized by state law and his or her professional scope of practice, to give direction, either orally or in writing, for the preparation and administration of a medication to be used in the treatment of substance use disorders;

(17) "Program sponsor" means the person named in the application for the licensure of an opioid treatment program who is responsible for the administrative operation of the opioid treatment program, and who assumes responsibility for all of its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program;

(18) "Secretary" means the secretary of the Cabinet for Health and Family Services or his or her designee;

(19) "Substance" means:

(a) Alcohol;

(b) A controlled substance; or

(c) Any chemical, gas, drug, or medication consumed which causes clinically and functionally significant impairment, such as health problems, disability, or failure to meet major responsibilities at work, school, or home;

(20) "Substance Abuse and Mental Health Services Administration" means the agency under the United States Department of Health and Human Services responsible for the accreditation and certification of medication-assisted treatment programs and that provides leadership, resources, programs, policies, information, data, contracts, and grants for the purpose of reducing the impact of substance use and mental or behavioral illness;

(21) "Substance use disorder" means patterns of symptoms resulting from use of a substance that the individual continues to take, despite experiencing problems as a result; or as defined in the most recent edition of the American Psychiatric

Association's Diagnostic and Statistical Manual of Mental Disorders;

(22) "Variance" means written permission granted by the secretary to a medication-assisted treatment program that a requirement of Sections 1 to 11 of this Act or administrative regulations promulgated pursuant to Sections 1 to 11 of this Act may be accomplished in a manner different from the manner set forth in Sections 1 to 11 of this Act or the associated administrative regulations; and

(23) "Waiver" means a formal, time-limited agreement between the designated oversight agency and the medication-assisted treatment program that suspends a rule, policy, or standard for a specific situation as long as the health and safety of patients is better served in the situation by suspension of the rule, policy, or standard than by enforcement.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) No person, partnership, association, or limited liability company may operate an opioid treatment program without first obtaining a license from the secretary in accordance with the provisions of this section and the administrative regulations lawfully promulgated pursuant to Sections 1 to 11 of this Act.

(2) A person, partnership, association, or limited liability company desiring a license to operate an opioid treatment program in this state shall file with the department an application in such form and with such information as the secretary shall prescribe, accompanied by an application fee.

(3) (a) The commissioner or his or her designee shall inspect each facility and review all documentation submitted with an application.

(b) The commissioner shall then provide a recommendation to the secretary whether to approve or deny the application for a license.

(c) The secretary shall issue a license if the facility is in compliance with the provisions of Sections 1 to 11 of this Act and with the administrative

regulations lawfully promulgated pursuant to Sections 1 to 11 of this Act.

(4) A license shall be issued in one (1) of three (3) categories:

(a) An initial one (1) year license shall be issued to an opioid treatment program establishing a new program or service for which there is insufficient consumer participation to demonstrate substantial compliance with Sections 1 to 11 of this Act and with all administrative regulations promulgated pursuant to Sections 1 to 11 of this Act;

(b) A provisional license shall be issued when an opioid treatment program seeks a renewal license, or is an existing program as of the effective date of this Act and is seeking an initial license, and the opioid treatment program is not in substantial compliance with Sections 1 to 11 of this Act and with all administrative regulations promulgated pursuant to Sections 1 to 11 of this Act, but does not pose a significant risk to the rights, health, and safety of a consumer. It shall expire not more than six (6) months from the date of issuance, and may not be consecutively reissued; or

(c) A renewal license shall be issued when an opioid treatment program is in substantial compliance with Sections 1 to 11 of this Act and with all administrative regulations promulgated pursuant to Sections 1 to 11 of this Act. A renewal license shall expire not more than one (1) year from the date of issuance.

(5) (a) At least sixty (60) days prior to the license expiration date, an application for renewal shall be submitted by the opioid treatment program to the secretary on a form furnished by the secretary. A license shall be renewed if the secretary determines that the applicant is in compliance with Sections 1 to 11 of this Act and with all administrative regulations promulgated pursuant to Sections 1 to 11 of this Act.

(b) A license issued to one (1) program location pursuant to this section is not

transferable or assignable. Any change of ownership of a licensed medication-assisted treatment program requires submission of a new application. The medication-assisted treatment program shall notify the secretary of any change of ownership within ten (10) days of the change and shall submit a new application within the time frame prescribed by the secretary.

(6) A person, partnership, association, or limited liability company that seeks to obtain or renew a license for an opioid treatment program in this state shall submit to the secretary the following documentation:

(a) Full operating name of the program as advertised;

(b) Legal name of the program as registered with the Office of the Secretary of State;

(c) Physical address of the program;

(d) Preferred mailing address for the program;

(e) E-mail address to be used by the primary contact for the program;

(f) Federal Employer Identification Number assigned to the program;

(g) All business licenses issued to the program by this state, the Department of Revenue, the Secretary of State, and all other applicable business entities;

(h) Documentation of each owner's medical license status;

(i) Brief description of all services provided by the program;

(j) Hours of operation;

(k) Legal name of the person registered as the owner of the program. If there is more than one (1) legal owner, each owner shall be listed separately, indicating the percentage of ownership;

(l) Medical director’s full name, medical license number, Drug Enforcement Administration registration number, and a list of all current certifications;

(m) For each employee of the program:

1. Employee's role and occupation within the program;

2. Full legal name;

3. Medical license, if applicable;

4. Drug Enforcement Administration registration number, if applicable;

5. Drug Enforcement Administration identification number to prescribe buprenorphine, if applicable, and

6. Number of hours per week worked at the program;

(n) Name and location address of all programs owned or operated by the applicant;

(o) Notarized signature of applicant;

(p) Check or money order for licensing fee and inspection fee;

(q) Verification of education and training for all physicians, counselors, and social workers practicing at or used by referral by the program, including but not limited to fellowships, additional education, accreditations, board certifications, and other certifications; and

(r) Confirmation from each prescriber practicing at the program that they have maintained a current account with the electronic system for monitoring controlled substances established pursuant to KRS 218A.202 for the three (3) months preceding the date of application.

(7) Upon satisfaction that an applicant has met all of the requirements of this section, the secretary shall issue a license to operate an opioid treatment program. An entity that obtains this license may possess, have custody or control of, and dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.

(8) The opioid treatment program shall display the current license in a prominent location where services are provided and in clear view of all patients.

(9) The secretary or his or her designee shall inspect on a periodic basis all opioid

treatment programs that are subject to Sections 1 to 11 of this Act and all administrative regulations adopted pursuant to Sections 1 to 11 of this Act to ensure continued compliance.

(10) (a) A license on the effective date of this Act shall remain in effect until such time as new administrative regulations promulgated pursuant to Sections 1 to 11 of this Act become effective.

(b) Upon the effective date of the new administrative regulations, a licensee shall file for a new license within six (6) months pursuant to the licensing procedures and requirements of this section and the new administrative regulations promulgated hereunder. The existing license shall remain effective until receipt of the new license.

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) No person, partnership, association, or limited liability company may operate an office-based medication-assisted treatment program without first obtaining a license from the secretary in accordance with the provisions of this section and the administrative regulations lawfully promulgated pursuant to Sections 1 to 11 of this Act.

(2) A person, partnership, association, or limited liability company desiring a license to operate an office based medication-assisted treatment program in this state shall file with the department an application in such form and with such information as the secretary shall prescribe, accompanied by an application fee.

(3) (a) The commissioner or his or her designee shall inspect and review all documentation submitted with an application.

(b) The commissioner shall then provide a recommendation to the secretary whether to approve or deny the application for a license.

(c) The secretary shall issue a license if the facility is in compliance with the

provisions of Sections 1 to 11 of this Act and with the administrative regulations lawfully promulgated pursuant to Sections 1 to 11 of this Act.

(4) A license shall be issued in one (1) of three (3) categories:

(a) An initial one (1) year license shall be issued to an office based medication-assisted treatment program establishing a new program or service for which there is insufficient consumer participation to demonstrate substantial compliance with Sections 1 to 11 of this Act and with all administrative regulations promulgated pursuant to Sections 1 to 11 of this Act;

(b) A provisional license shall be issued when an office-based medication-assisted treatment program seeks a renewal license, or is an existing program as of the effective date of this Act and is seeking an initial license, and the office-based medication-assisted treatment program is not in substantial compliance with Sections 1 to 11 of this Act and with all administrative regulations promulgated pursuant to Sections 1 to 11 of this Act, but does not pose a significant risk to the rights, health, and safety of a consumer. It shall expire not more than six (6) months from the date of issuance, and may not be consecutively reissued; or

(c) A renewal license shall be issued when an office-based medication-assisted treatment program is in substantial compliance with Sections 1 to 11 of this Act and with all administrative regulations promulgated pursuant to Sections 1 to 11 of this Act. A renewal license shall expire not more than one (1) year from the date of issuance.

(5) (a) At least sixty (60) days prior to the license expiration date, an application for renewal shall be submitted by the office-based medication-assisted treatment program to the secretary on a form furnished by the secretary. A license shall be renewed if the secretary determines that the applicant is in compliance with Sections 1 to 11 of this Act and with all administrative

regulations promulgated pursuant to Sections 1 to 11 of this Act.

(b) A license issued to one (1) program location pursuant to this section is not transferable or assignable. Any change of ownership of a licensed medication-assisted treatment program requires submission of a new application. The medication-assisted treatment program shall notify the secretary of any change of ownership within ten (10) days of the change and shall submit a new application within the time frame prescribed by the secretary.

(6) A person, partnership, association, or limited liability company that seeks to obtain or renew a license for an office-based medication-assisted treatment program in this state shall submit to the secretary the following documentation:

(a) Full operating name of the program as advertised;

(b) Legal name of the program as registered with the Office of the Secretary of State;

(c) Physical address of the program;

(d) Preferred mailing address for the program;

(e) E-mail address to be used by the primary contact for the program;

(f) Federal Employer Identification Number assigned to the program;

(g) All business licenses issued to the program by this state, the Department of Revenue, the Secretary of State, and all other applicable business entities;

(h) Documentation of each owner's medical license status;

(i) Brief description of all services provided by the program;

(j) Hours of operation;

(k) Legal name of the person registered as the owner of the program. If there is more than one (1) legal owner, each owner shall be listed separately, indicating the percentage of ownership;

(l) Medical director's full name, medical license number, Drug Enforcement

Administration registration number, and a list of all current certifications;

(m) For each employee of the program:

1. Employee's role and occupation within the program;

2. Full legal name;

3. Medical license, if applicable;

4. Drug Enforcement Administration registration number, if applicable;

5. Drug Enforcement Administration identification number to prescribe buprenorphine, if applicable, and

6. Number of hours per week worked at the program;

(n) Name and location address of all programs owned or operated by the applicant;

(o) Notarized signature of applicant;

(p) Check or money order for licensing fee and inspection fee;

(q) Verification of education and training for all physicians, counselors, and social workers practicing at or used by referral by the program, including but not limited to fellowships, additional education, accreditations, board certifications, and other certifications; and

(r) Confirmation from each prescriber practicing at the program that they have maintained a current account with the electronic system for monitoring controlled substances established pursuant to KRS 218A.202 for the three (3) months preceding the date of application.

(7) Upon satisfaction that an applicant has met all of the requirements of this section, the secretary shall issue a license to operate an office-based medication-assisted treatment program. An entity that obtains this license may possess, have custody or control of, and dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.

(8) The office-based medication-assisted treatment program shall display the current license in a prominent location where services are provided and in clear view of all patients.

(9) The secretary or his or her designee shall inspect on a periodic basis all office based medication-assisted treatment programs that are subject to Sections 1 to 11 of this Act and all administrative regulations adopted pursuant to Sections 1 to 11 of this Act to ensure continued compliance.

(10) (a) A person, partnership, association, or limited liability company operating a medication-assisted treatment program shall be permitted to continue operation until the new administrative regulations promulgated pursuant to Sections 1 to 11 of this Act become effective.

(b) Upon the effective date of the new administrative regulations, a person, partnership, association, or limited liability company shall file for a new license within six (6) months pursuant to the licensing procedures and requirements of this section and the new administrative regulations promulgated hereunder. The existing procedures shall remain effective until receipt of the new license.

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) A medication-assisted treatment program shall be licensed and registered in this state with the Secretary of State, the Department of Revenue, and all other applicable business or licensing entities.

(2) A program sponsor of a medication-assisted treatment program shall be a licensed physician pursuant to KRS Chapter 311 and in good standing with the Kentucky Board of Medical Licensure.

(3) A medication-assisted treatment program shall designate a medical director. If the medication-assisted treatment program is accredited by a Substance Abuse

and Mental Health Services Administration-approved accrediting body that meets nationally accepted standards for providing medication-assisted treatment, including the Commission on Accreditation of Rehabilitation Facilities or the Joint Commission, then the program may designate a medical director to oversee all facilities associated with the accredited medication-assisted treatment program. The medical director shall be responsible for the operation of the medication-assisted treatment program, and may delegate the day-to-day operation of the medication-assisted treatment program as provided in the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act. Within ten (10) days after termination of a medical director, the medication-assisted treatment program shall notify the commissioner of the identity of another medical director for that program. Failure to have a medical director practicing at the program may be the basis for a suspension or revocation of the program license. The medical director shall:

(a) Have a full, active, and unencumbered license to practice medicine or osteopathy from the Kentucky Board of Medical Licensure, and be in good standing and not under any probationary restrictions;

(b) Meet both of the following requirements:

1. If the physician prescribes a partial opioid agonist, he or she shall complete the requirements for the federal Drug Addiction Treatment Act of 2000; and

2. Complete other programs and continuing education requirements as further described in the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act;

(c) Practice at the licensed medication-assisted treatment program a sufficient number of hours, based upon the type of medication-assisted license issued pursuant to Sections 1 to 11 of this Act, to ensure regulatory compliance

and carry out those duties specifically assigned to the medical director as further described in the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act;

(d) Be responsible for monitoring and ensuring compliance with all requirements related to the licensing and operation of the medication-assisted treatment program;

(e) Supervise, control, and direct the activities of each individual working or operating at the medication-assisted treatment program, including any employee, volunteer, or individual under contract, who provides medication-assisted treatment at the program or is associated with the provision of that treatment; and

(f) Complete other requirements prescribed by the secretary by administrative regulation.

(4) Each medication-assisted treatment program shall designate counseling staff, either employees or those used on a referral-basis by the program, who meet the requirements of Sections 1 to 11 of this Act and the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act. The individual members of the counseling staff shall be:

(a) A physician licensed to practice medicine or osteopathy pursuant to KRS Chapter 311 who is certified by the American Board of Psychiatry and Neurology, Inc.;

(b) A certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate certified or licensed pursuant to KRS Chapter 309;

(c) A counselor, marriage and family therapist, or social worker licensed or certified pursuant to KRS Chapter 335 with a master's level education with a specialty or specific training in treatment for substance use disorders;

(d) A psychologist licensed or certified pursuant to KRS Chapter 319 with a master's level education with a specialty or specific training in treatment for substance use disorders;

(e) An individual with a bachelor's degree in social work or another relevant human services field operating under the direct supervision of a licensed clinical alcohol and drug counselor, so long as the individual applies for certification as an alcohol and drug counselor within three (3) years of the date of employment; or

(f) An individual with a graduate degree in social work or another relevant human services field actively working toward licensure or certification and operating under supervision of a licensed or certified professional or a licensed clinical alcohol and drug counselor.

(5) A medication-assisted treatment program shall be eligible for, and not prohibited from, enrollment with the Medicaid program or any health benefit plan. Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program shall receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or Medicaid denying coverage for such treatment, except that the secretary may grant a variance from this requirement pursuant to Section 6 of this Act. The program shall also document whether a patient has no insurance. At the option of the medication-assisted treatment program, treatment may commence prior to billing.

(6) A medication-assisted treatment program shall apply for and receive approval as required from the United States Drug Enforcement Administration, Center for Substance Abuse Treatment, or an organization designated by the Substance Abuse and Mental Health and Mental Health Administration.

(7) All persons employed by a medication-assisted treatment program shall comply

with the requirements for the operation of a medication-assisted treatment program established within Sections 1 to 11 of this Act or by any administrative regulation adopted pursuant to Sections 1 to 11 of this Act.

(8) All employees of an opioid treatment program shall furnish fingerprints for a state and federal criminal records check by the Kentucky State Police and the Federal Bureau of Investigation. The fingerprints shall be accompanied by a signed authorization for the release of information and retention of the fingerprints by the Kentucky State Police and the Federal Bureau of Investigation.

(9) A medication-assisted treatment program shall not be owned by, nor shall it employ or associate with, any physician or prescriber:

(a) Whose Drug Enforcement Administration number is not currently full, active, and unencumbered;

(b) Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by and is not full, active, and unencumbered in any jurisdiction; or

(c) Whose license is anything other than a full, active, and unencumbered license to practice by the Kentucky Board of Medical Licensure, and, who is in good standing and not under any probationary restrictions.

(10) A person may not dispense any medication-assisted treatment medication, including a controlled substance as defined by KRS 218A.010, on the premises of a licensed medication-assisted treatment program, unless he or she is a physician or pharmacist licensed in this state and employed by the medication-assisted treatment program unless the medication-assisted treatment program is a federally-certified narcotic treatment program. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician shall access the electronic system for monitoring controlled substances established pursuant to

KRS 218A.202 to ensure the patient is not seeking medication-assisted treatment medications that are controlled substances from multiple sources, to assess potential adverse drug interactions, or both. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician shall also ensure that the medication-assisted treatment medication utilized is related to an appropriate diagnosis of a substance use disorder and approved for such usage. The physician shall also review the electronic system no less than quarterly and at each patient's physical examination pursuant to KRS 218A.202(8).

(11) A medication-assisted treatment program responsible for medication administration shall comply with:

(a) The Kentucky Board of Pharmacy administrative regulations;

(b) The Kentucky Board of Nursing administrative regulations;

(c) All applicable federal laws and regulations relating to controlled substances; and

(d) Any requirements as specified in the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act.

(12) Each medication-assisted treatment program location shall be licensed separately, regardless of whether the program is operated under the same business name or management as another program.

(13) A medication-assisted treatment program shall develop and implement patient protocols, treatment plans, or treatment strategies and profiles, which shall include but not be limited by the following guidelines:

(a) When a physician diagnoses an individual as having a substance use disorder, the physician may treat the substance use disorder by managing it with medication in doses not exceeding those approved by the United States Food and Drug Administration as indicated for the treatment of substance use disorders and not greater than those amounts described in the

administrative regulations promulgated pursuant to Sections 1 to 11 of this Act. The treating physician and treating staff member's diagnoses and treatment decisions shall be made according to accepted and prevailing standards of medical care;

(b) A medication-assisted treatment program shall maintain a record of all of the following:

1. Medical history and physical examination of the individual;

2. The diagnosis of substance use disorder of the individual;

3. The plan of treatment proposed, the patient's response to the treatment, and any modification to the plan of treatment;

4. The dates on which any medications were prescribed, dispensed, or administered, the name and address of the individual for whom the medications were prescribed, dispensed, or administered, and the amounts and dosage forms for any medications prescribed, dispensed, or administered;

5. A copy of the report made by the physician or staff member to whom referral for evaluation was made, if applicable; and

6. A copy of the coordination of care agreement, which is to be signed by the patient, treating physician, and treating staff member. If a change of treating physician or treating staff member takes place, a new agreement shall be signed. The coordination of care agreement shall be updated or reviewed at least annually. If the coordination of care agreement is reviewed, but not updated, this review shall be documented in the patient's record. The coordination of care agreement shall be provided in a form prescribed and made available by the secretary;

(c) A medication-assisted treatment program shall report information, data,

statistics, and other information as directed in Sections 1 to 11 of this Act and the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act to required agencies and other authorities;

(d) A physician, physician assistant, or advanced practice registered nurse shall perform a physical examination of a patient on the same day that the prescriber initially prescribes, dispenses, or administers a medication-assisted treatment medication to a patient and at intervals as required in the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act;

(e) A physician, physician assistant, or advanced practice registered nurse shall not see or treat more than six (6) patients per hour;

(f) A psychiatrist, alcohol and drug abuse counselor, psychologist, counselor, or social worker shall perform a biopsychosocial assessment, including but not limited to a mental status examination of a patient on the same day or nor more than seven (7) days prior to the day that the physician initially prescribes, dispenses, or administers a medication-assisted treatment medication to a patient and at intervals as required in the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act;

(g) A prescriber authorized to prescribe a medication-assisted treatment medication who practices at a medication-assisted treatment program is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing a medication-assisted treatment medication. The prescriber shall comply with all state and federal requirements for tamper-resistant prescription paper. In addition to any other requirements imposed by law or administrative regulation, the prescriber shall notify the secretary and appropriate law enforcement agencies in writing within twenty-four (24) hours following

any theft or loss of a prescription blank or breach of any other method of prescribing a medication-assisted treatment medication; and

(h) A medication-assisted treatment program shall have a drug testing program to ensure a patient is in compliance with the treatment strategy.

(14) A medication-assisted treatment program shall only prescribe, dispense, or administer liquid methadone to patients pursuant to the restrictions and requirement of the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act.

(15) A medication-assisted treatment program shall immediately notify the secretary, or his or her designee, in writing of any changes to its operations that affect the medication-assisted treatment program's continued compliance with licensure requirements.

(16) If a physician treats a patient with more than sixteen (16) milligrams per day of buprenorphine, then clear medical notes shall be placed in the patient's medical file indicating the clinical reason or reasons for the higher level of dosage.

(17) If a physician is not the patient's obstetrical or gynecological provider, the physician shall consult with the patient's obstetrical or gynecological provider to the extent possible to determine whether the prescription is appropriate for the patient.

(18) A practitioner providing medication-assisted treatment may perform certain aspects of telehealth if permitted under his or her scope of practice.

(19) The physician shall follow the recommended manufacturer's tapering schedule for the medication-assisted treatment medication. If the schedule is not followed, the physician shall document that in the patient's medical record and the clinical reason why the schedule was not followed. The secretary may investigate a medication-assisted treatment program if a high percentage of its patients are not following the recommended tapering schedule.

➔SECTION 6. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) A medication-assisted treatment program shall not be located, operated, managed, or owned at the same location where a pain management facility, as licensed and defined in KRS 218A.175, is located.

(2) A medication-assisted treatment program shall not have procedures for offering a bounty, monetary, equipment, or merchandise reward, or free services for individuals in exchange for recruitment of new patients into the facility.

(3) A medication-assisted treatment program shall not be located within one-half (1/2) mile of a public or private licensed child-care center or public or private elementary or secondary school. Existing medication-assisted treatment programs, including both opioid treatment programs and office-based medication-assisted treatment programs, that are located within one-half (1/2) mile of a public or private licensed child-care center or public or private elementary or secondary school, shall be granted a variance, if the facility demonstrates adequate patient population controls and that it may otherwise meet the requirements of Sections 1 to 11 of this Act and the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act.

(4) (a) The secretary may grant a waiver or a variance from any licensure standard, or portion thereof, for the period during which the license is in effect.

(b) A request for a waiver or variance of licensure standards shall be in writing to the secretary and shall include:

1. The specific section of Sections 1 to 11 of this Act or administrative regulations promulgated pursuant to Sections 1 to 11 of this Act for which a waiver or variance is sought;

2. The rationale for requesting the waiver or variance;

3. Documentation by the medication-assisted treatment program's medical director to the secretary that describes how the program will maintain the quality of services and patient safety if the waiver or variance is granted; and

4. The consequences of not receiving approval of the requested waiver or variance.

(c) The secretary shall issue a written statement to the medication-assisted treatment program granting or denying a request for a waiver or variance of program licensure standards.

(d) The medication-assisted treatment program shall maintain a file copy of all requests for waivers or variances and the approval or denial of the requests for the period during which the license is in effect.

(e) The department shall inspect each medication-assisted treatment program prior to a waiver or variance being granted, including a review of patient records, to ensure and verify that any waiver or variance request meets the spirit and purpose of Sections 1 to 11 of this Act and the administrative regulations promulgated pursuant to Sections 1 to 11 this Act. The department may verify, by unannounced inspection, that the medication-assisted treatment program is in compliance with any waiver or variance granted by the secretary for the duration of such waiver or variance.

➔SECTION 7. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) The department shall inspect each opioid treatment program annually, including a review of the patient records, to ensure that the program complies with Sections 1` to 11 of this Act and the applicable administrative regulations. A pharmacist, employed or contracted by the secretary, licensed in this state, and a law enforcement officer may be present at each inspection.

(2) The department shall perform unannounced complaint and verification inspections at office based medication-assisted treatment programs, including a review of the patient records, to ensure that the program complies with Sections 1 to 11 of this Act and the applicable administrative regulations. A pharmacist, employed or contracted by the secretary, licensed in this state and a law enforcement officer may be present at each inspection.

(3) During an onsite inspection, the inspectors shall make a reasonable attempt to discuss each violation with the medical director or other owners of the medication-assisted treatment program before issuing a formal written notification.

(4) Any action taken to correct a violation shall be documented in writing by the medical director or other owners of the medication-assisted treatment program and may be verified by follow-up visits by the department.

(5) Notwithstanding the existence or pursuit of any other remedy, the secretary may, in the manner provided by law, maintain an action in the name of the state for an inspection warrant against any person, partnership, association, or limited liability company to allow any inspection or seizure of records in order to complete any inspection allowed by Sections 1 to 11 of this Act or the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act, or to meet any other purpose of Sections 1 to 11 of this Act or the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act.

(6) When possible, inspections for annual licensure by the medication-assisted treatment programs will be done consecutively or concurrently. However, this provision does not limit the ability to conduct unannounced inspections pursuant to a complaint.

➔SECTION 8. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) The secretary may, by order, impose a ban on the admission of patients or reduce patient capacity of a medication-assisted treatment program, or any combination thereof, when he or she finds upon inspection of the medication-assisted treatment program that the licensee is not providing adequate care under the medication-assisted treatment program's existing patient quota, and that a reduction in quota or imposition of a ban on admissions, or any combination thereof, would place the licensee in a position to render adequate care. Any notice to a licensee of reduction in quota or ban on new admissions shall include the terms of the order, the reasons therefor, and the date set for compliance.

(2) The secretary shall deny, suspend, or revoke a license issued pursuant to Sections 1 to 11 of this Act if the provisions of Sections 1 to 11 of this Act or of the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act are violated. The secretary may revoke a program's license and prohibit all physicians and licensed disciplines associated with that medication-assisted treatment program from practicing at the program location based upon an annual, periodic, complaint, verification, or other inspection and evaluation.

(3) Before any license is denied, suspended, or revoked, written notice shall be given to the licensee, stating the grounds for the denial, suspension, or revocation.

(4) An applicant or licensee has ten (10) working days after receipt of the secretary's order denying, suspending, or revoking a license to request a formal hearing contesting the denial, suspension, or revocation of a license under this section. If a formal hearing is requested, the applicant or licensee and the secretary shall proceed in accordance with the provisions of KRS Chapter 13B.

(5) If a license is denied or revoked, a new application for a license shall be considered by the secretary if, when, and after the conditions upon which the denial or revocation was based have been corrected and evidence of this fact has been furnished. A new license shall then be granted after proper inspection, if

applicable, has been made and all provisions of Sections 1 to 11 of this Act and the administrative regulations promulgated pursuant to Sections 1 to 11 of this Act have been satisfied.

(6) Any applicant or licensee who is dissatisfied with the decision of the secretary as a result of the hearing provided in this section may, within thirty (30) days after receiving notice of the decision, petition the Circuit Court of Franklin County, for judicial review of the decision.

(7) The court may affirm, modify, or reverse the decision of the secretary and either the applicant or licensee or the secretary may appeal from the court's decision to the Court of Appeals.

(8) If the license of a medication-assisted treatment program is denied, suspended, or revoked, the medical director of the program, any owner of the program, or owner or lessor of the medication-assisted treatment program property shall cease to operate the clinic, facility, office, or program as a medication-assisted treatment program as of the effective date of the denial, suspension, or revocation. The owner or lessor of the medication-assisted treatment program property is responsible for removing all signs and symbols identifying the premises as a medication-assisted treatment program within thirty (30) days. Any administrative appeal of such denial, suspension, or revocation shall not stay the denial, suspension, or revocation.

(9) Upon the effective date of the denial, suspension, or revocation, the medical director of the medication-assisted treatment program shall advise the secretary and the Kentucky Board of Pharmacy of the disposition of all medications located on the premises. The disposition is subject to the supervision and approval of the secretary. Medications that are purchased or held by a medication-assisted treatment program that is not licensed may be deemed adulterated.

(10) If the license of a medication-assisted treatment program is suspended or

revoked, any person named in the licensing documents of the program, including persons owning or operating the medication-assisted treatment program, may not, as an individual or as part of a group, apply to operate another medication-assisted treatment program for up to five (5) years after the date of suspension or revocation. The secretary may grant a variance pursuant to Section 6 of this Act to the prohibition of this subsection.

(11) The period of suspension for the license of a medication-assisted treatment program shall be prescribed by the secretary, but shall not exceed one (1) year.

➔SECTION 9. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

(1) A person, partnership, association, or limited liability company which establishes, conducts, manages, or operates a medication-assisted treatment program without first obtaining a license, or who violates any provision of Sections 1 to 11 of this Act or any administrative regulation promulgated pursuant to Sections 1 to 11 of this Act, shall be assessed a civil penalty by the secretary in accordance with this subsection. Each day of continuing violation after conviction shall be considered a separate violation:

(a) If a medication-assisted treatment program or an owner or medical director is found to be in violation of any provision of Sections 1 to 11 of this Act, unless otherwise noted in this subsection, the secretary may limit, suspend, or revoke the program's license;

(b) If a program's medical director knowingly and intentionally misrepresents actions taken to correct a violation, the secretary may, in addition to any other penalty available by law, impose a civil penalty not to exceed ten thousand dollars ($10,000) and, in the case of an owner-operator medication-assisted treatment program, limit or revoke a medication-assisted treatment program's license;

(c) If an owner or medical director of a medication-assisted treatment program concurrently operates an unlicensed medication-assisted treatment program, the secretary may, in addition to any other penalty available by law, impose a civil penalty upon the owner or medical director, or both, not to exceed five thousand dollars ($5,000) per day;

(d) If an owner of a medication-assisted treatment program that requires a license under Sections 1 to 11 of this Act fails to apply for a new license for the program upon a change of ownership and operates the program under new ownership, the secretary may, in addition to any other penalty available by law, impose a civil penalty upon the owner, not to exceed five thousand dollars ($5,000); or

(e) If a physician:

1. Operates, owns, or manages an unlicensed medication-assisted treatment program that is required to be licensed pursuant to Sections 1 to 11 of this Act;

2. Knowingly prescribes or dispenses or causes to be prescribed or dispensed a medication-assisted treatment medication through misrepresentation or fraud;

3. Procures, or attempts to procure, a license for a medication-assisted treatment program for any other person by making or causing to be made any false representation;

the secretary may assess a civil penalty of not more than twenty thousand dollars ($20,000). The penalty may be in addition to or in lieu of any other action that may be taken by the secretary or any other board, court, or entity.

(2) Notwithstanding the existence or pursuit of any other remedy, the secretary may, in the manner provided by law, maintain an action in the name of the state for an

injunction against any person, partnership, association, or limited liability company to restrain or prevent the establishment, conduct, management, or operation of any medication-assisted treatment program or violation of any provision of Sections 1 to 11 of this Act or any administrative regulation promulgated thereunder without first obtaining a license in the manner herein provided.

(3) In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the secretary shall consider the following factors:

(a) The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the medication-assisted treatment program's actions or the actions of the medical director or any practicing physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or administrative regulations were violated;

(b) What actions, if any, the owner or medical director took to correct the violations;

(c) Whether there were any previous violations at the medication-assisted treatment program; and

(d) The financial benefits that the medication-assisted treatment program derived from committing or continuing to commit the violation.

(4) Upon finding that a physician has violated the provisions of Sections 1 to 11 of this Act or administrative regulations adopted pursuant to Sections 1 to 11 of this Act, the secretary shall provide notice of the violation to the applicable licensing board.

➔SECTION 10. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

An advertisement made by or on behalf of a medication-assisted treatment program

through public media, such as a telephone directory, medical directory, newspaper, periodical, outdoor advertising, radio, television, or through written or recorded communication, concerning the treatment of substance use disorders, as defined in Section 2 of this Act, shall include the name of, at a minimum, the medical director responsible for the content of the advertisement.

➔SECTION 11. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO READ AS FOLLOWS:

The secretary shall promulgate administrative regulations in accordance with the provisions of KRS Chapter 13A for the licensure of medication-assisted treatment programs to ensure adequate care, treatment, health, safety, welfare, and comfort of patients at these facilities and in these programs. The administrative regulations shall include, at a minimum:

(1) The process to be followed by an applicant seeking a license;

(2) The qualifications and supervision of licensed and unlicensed personnel at a medication-assisted treatment program and training requirements for facility health care practitioners who are not regulated by another board;

(3) The provision and coordination of patient care, including the development of a written plan of care and patient contract;

(4) The management, operation, staffing, and equipment of a medication-assisted treatment program;

(5) The clinical, medical, patient, and business records kept by a medication-assisted treatment program;

(6) The procedures for inspections, review of utilization, and quality of patient care;

(7) The standards and procedures for the general operation of a medication-assisted treatment program, including facility operations, physical operations, infection control requirements, health and safety requirements, and quality assurance;

(8) Identification of drugs that may be used to treat substance use disorders that

identify a facility as a medication-assisted treatment program;

(9) Any other criteria that identify a facility as a medication-assisted treatment program;

(10) The standards and procedures to be followed by an owner in providing supervision, direction, and control of individuals employed by or associated with a medication-assisted treatment program;

(11) Data collection and reporting requirements;

(12) Criteria and requirements related to specific medication-assisted treatment medications; and

(13) Other standards or requirements as the secretary determines are appropriate.